

INTERNATIONAL SEARCH REPORT

International Application No.
P 03/14077

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/436 A61K31/57 A61K31/167 A61K31/137 A61K31/135
A61K31/44 A61K31/18 A61P11/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 90 14826 A (FISONS PLC ;FUJISAWA PHARMACEUTICAL CO (JP)) 13 December 1990 (1990-12-13) example B page 6, line 24 - line 26 ---	1-9
Y	WO 97 10806 A (HATA TAKEHISA ;MURATA SABURO (JP); SHIMOJO FUMIO (JP); TOKUNAGA YU) 27 March 1997 (1997-03-27) page 9, line 26 - line 27 page 16, line 29 - line 32 --- -/--	1-9

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

27 January 2004

Date of mailing of the international search report

12/02/2004

Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>CONDEMI JOHN J: "Comparison of the efficacy of formoterol and salmeterol in patients with reversible obstructive airway disease: A multicenter, randomized, open-label trial" CLINICAL THERAPEUTICS, vol. 23, no. 9, September 2001 (2001-09), pages 1529-1541, XP002268183 ISSN: 0149-2918 * page 1530, left-hand column, Conclusions *</p> <p>---</p>	1-9
Y	<p>AZIZ I ET AL: "Comparative trough effects of formoterol and salmeterol on lymphocyte beta2-adrenoceptor - regulation and bronchodilatation" EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, vol. 55, no. 6, August 1999 (1999-08), pages 431-436, XP002268184 ISSN: 0031-6970 * page 431, right-hand column, Conclusion *</p> <p>---</p>	1-9
Y	<p>LAPA E SILVA JOSE R ET AL: "Modulation of experimental bronchopulmonary allergy by anti-inflammatory compounds" CIENCIA E CULTURA (SAO PAULO), vol. 52, no. 6, November 2000 (2000-11), pages 386-392, XP008026921 ISSN: 0009-6725 page 389, left-hand column, paragraph 2 page 391, left-hand column, paragraph 2 -----</p>	1-9

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 2, 3, 7 and 9 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1 - 4 and 6 - 9 relate to a compound defined by reference to a desirable characteristic or property, namely "beta2-agonist". The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the following beta2-agonists: salmeterol, formoterol, albuterol, bitolterol, fenoterol, isoetharine, metaproterenol, pirbuterol, terbutaline and salbutamol (description, page 3, 2nd paragraph).

Present claims 1 - 3 and 5 - 9 relate to an extremely large number of possible compounds given by the expression "(FK506) derivatives". Support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds mentioned in the examples.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9014826	A	13-12-1990	JP 3291225 A	20-12-1991
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			EP 0851753 A1	08-07-1998
			WO 9710806 A1	27-03-1997
			JP 3266005 B2	18-03-2002
			JP 9143054 A	03-06-1997
			JP 2000505050 T	25-04-2000
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			TW 429153 B	11-04-2001
			US 6361760 B1	26-03-2002
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